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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/527,440	03/17/2000	Hiroki Nakae	HIRA.0003	3095
7590 01/29/2004				
Stanley P Fisher Reed Smith Hazel & Thomas LLP 3110 Fairview Park Drive Suite 1400 Falls Church, VA 22042-4503			EXAMINER CLOW, LORI A	
			ART UNIT 1631	PAPER NUMBER

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/527,440	NAKAE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 30-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 30-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicants' arguments, filed 14 October 2003, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-4 and 30-37 are currently pending.

The rejection of claims 1-4 and 30-37 under 35 USC 103(a) as being unpatentable over US 6,251,588, in view of WO 98/06872, in further view of 6,083,763 has been withdrawn in view of Applicant's arguments.

### ***Claim Objections***

Claims 2-4 recite "A primer design system". The claims should read "**The** primer design system".

Claims 3 and 31 include the term  $T_m$ . This should be spelled out to read melting temperature, at least once in the claims.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 30-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is a new grounds of rejection.

Claims 1, 30, and 34 are confusing in that the means for using each of the predicted exons as a template to design one corresponding primer pair for each predicted exon is followed, in the same step, by a means for designing corresponding primer pairs for the predicted exons simultaneously. Perhaps applicant intends for the means for designing simultaneously to be a separate step. Clarification is requested.

The language of claim 3 is confusing. Perhaps applicant intends for the claim to read “A primer design system according to claim 2, **wherein** said selection conditions..”

Claims 4, 32, and 34 recite “a means for evaluating specificity of each designed primer or primer pair”. This is confusing in that claim 1 is only designing primer **pairs** and not single primers. Clarification is requested.

Claim 4 is indefinite in that included is a means for evaluating specificity. What is the means for evaluating specificity? There are many ways to evaluate specificity in the art. Is this evaluated by a sequence alignment program, such as BLAST or by some other means?

Claim 31 recites “wherein said **extraction** conditions”. Perhaps applicant intends this to read “wherein said **selection** conditions”. Clarification is requested.

Claim 33 recites “dividing fragments of genomic DNA **as** templates”. Perhaps applicant intends this to read “dividing fragments of genomic DNA **into** template”. Clarification is requested.

Claim 33 recites a “system further comprising randomly dividing fragments”. This is confusing in that the system cannot itself randomly divide fragments. Perhaps applicant intends this to read “further comprising **a means** for randomly dividing fragments”. Clarification is requested.

Claim 34 recites in the first step a “database including a plurality of DNA nucleotide sequences. This should read a plurality of genomic DNA sequences for agreement with the second line.

Claims 35-37 recite a system wherein the means for evaluating specificity evaluates each designed primer. This is unclear. Perhaps applicant intends the claims to read “a primer design system according to claim 34, wherein the system is capable of evaluating each designed primer”. Clarification is requested.

Claim 37 recites “conducting **justification** checks”. Perhaps Applicant intends this to read “conducting **specificity** checks”. Clarification is requested.

Claim 37 also recites “”on **each multiplication** region”. Perhaps Applicant intends this to read “on **an amplification** region”. Clarification is requested.

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Claim 37 also recites "positioned elsewhere on the DNA". This is confusing because the primer is not on the DNA. Perhaps Applicant means that the sequence is elsewhere in the DNA. Clarification is requested.

No claims are allowed.

### *Inquiries*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (571) 272-0549.

January 23, 2004  
Lori A. Clow, Ph.D.  
Art Unit 1631  
*Lori A. Clow*

MARJORIE MORAN  
PATENT EXAMINER

*Marjorie A. Moran*